

201-15174

Anh Nguyen

04/12/04 12:18 PM

To: NCIC HPV@EPA

cc:

Subject: Environmental Defense comments on the Gas Oils Category

----- Forwarded by Anh Nguyen/DC/USEPA/US on 04/12/2004 12:16 PM -----



rdenison@environmentaldefense.org

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To: NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, Karen Boswell/DC/USEPA/US@EPA, twerdokl@api.org, grayt@api.org

cc: lucierg@msn.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on the Gas Oils Category

(Submitted via Internet 4/12/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and twerdokl@api.org, grayt@api.org)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for the Gas Oils Category.

The test plan and robust summaries for the proposed gas oils category were submitted by the American Petroleum Institute. This is a very complex test plan, which likely involves hundreds of chemicals with varying compositions in different mixtures. There are not CAS numbers that neatly correspond to the various gas oil mixtures, although Appendix A provides a list of some 28 CAS numbers and corresponding stream descriptions. The materials included in this test plan apparently represent a generic class of petroleum substances known as middle distillates used in diesel engines, industrial and domestic heating oils and several other uses. In general, the test plan and robust summaries are informative and address the requirements of the HPV program.

The sponsor has subdivided this proposed category into three groups; gas oil streams rich in saturated hydrocarbons, gas oils that are predominantly aromatic hydrocarbons and distillate fuels. Each of the subcategories is evaluated to determine if data are adequate to meet HPV requirements. We recognize that the various gas oils represent a continuum with varying amounts of saturated hydrocarbons and aromatic hydrocarbons, and we agree that the sponsor's approach is both reasonable and tractable. One of the figures in the test plan indicates that there are at least 86 different representative samples of gas oils along this continuum.

However, we are concerned that the mixtures contain various heteroatoms (N, O and S) and also various metals. The normal ranges of percentages of the heteroatoms and metals in individual mixtures need to be presented before we can fully endorse the proposed subcategorization of the gas oils.

The sponsor proposes to conduct a number of tests on the three subcategories. These tests include a combined reproductive/developmental toxicity study on each of the three subcategories, full ecotoxicity studies on representative samples of the predominantly saturated hydrocarbons and the predominantly aromatic hydrocarbons subcategories, along with biodegradation studies on selected gas oils. We agree with these proposals as they do reflect data inadequacies for several HPV endpoints, but we do have some concerns regarding experimental designs for the proposed studies.

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In particular, we question the selection of the dermal route for the reproductive/developmental studies because no pharmacokinetic information was presented to indicate the proportion of various constituents of the gas oils which reach the systemic circulation following dermal application. Such information is critical for making an informed judgment as to whether or not the dermal route is most appropriate. Other comments are provided below:

1. The gas oils appear to possess a variety of toxic properties, including immunotoxicity, kidney toxicity, genetic toxicity, bone marrow effects and tumor promoting activity. Does the sponsor have any information on which constituents in gas oils are causing each of these effects?

2. The test plan includes considerable discussion on the presence of olefins in the gas oil mixtures. We agree that the test substances used in the mammalian and ecotoxicity tests should include a small amount of olefins, somewhere in the range of 2-5%. We also note that the sponsor has previously submitted a test plan on the higher olefins associated with petroleum products.

3. No information is provided on the amounts of gas oils released into the environment when they are used in various ways. If this information is available it should be provided in the test plan, and at least a general discussion of release and exposure potential would be very helpful.

Thank you for this opportunity to comment.

George Lucier, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense